Elitek® (rasburicase)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for a single course of treatment, consisting of 5 days of therapy
- Renewal: Prior authorization validity may NOT be renewed

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 45 billable units daily for 5 days; one 5-day therapy course only

III. Initial Approval Criteria

Prior authorization validity is provided in the following conditions:

Hyperuricemia due to Tumor Lysis † ‡ Φ [1,6]

- Member is at least 1 month of age; **AND**
- Member does NOT have any FDA labeled contraindications to the requested agent (e.g., deficiency in glucose-6-phosphate dehydrogenase (G6PD), history of reactions to rasburicase including: anaphylaxis, severe hypersensitivity, hemolysis, or methemoglobinemia); **AND**
- Member must be receiving chemotherapy for leukemia, lymphoma, or solid tumors; **AND**
  - Used as prophylactic therapy in members whose chemotherapy is expected to result in tumor lysis and subsequent elevation of plasma uric acid; **AND**
    - Member must be at high-risk* for developing hyperuricemia; **OR**
  - Used for treatment in members who develop hyperuricemia despite standard prophylactic therapies (i.e., hydration, allopurinol, febuxostat, etc.)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

*Risk factors for development of tumor lysis syndrome and subsequent hyperuricemia [4,6,16]
– High Risk Tumor Type (i.e., Burkitt lymphoma/leukemia; lymphoblastic lymphomas; ALL; DLBCL; other tumor types with high proliferative rate or high sensitivity to cytotoxic therapy) or members receiving treatment with high-risk medications (e.g., venetoclax, chemoimmunotherapy, lenalidomide, and obinutuzumab)
– Progressive disease after small-molecule inhibitor therapy

- Member with bulky disease or large tumor burden (i.e., any lymph node ≥10 cm; elevated LDH ≥2x ULN; absolute lymphocyte count ≥25,000/mcL; white blood cell count >50,000/mcL; organ infiltration; or bone marrow involvement)
- Spontaneous tumor lysis syndrome development
- Dehydration, volume depletion, or situations where adequate hydration may be difficult or impossible
- Renal disease or renal involvement by tumor (i.e., pre-existing nephropathy or exposure to nephrotoxins, oliguria and/or acidic urine)
- Pre-existing hyperuricemia (serum/plasma uric acid > 7.5mg/dl) or hyperphosphatemia (serum/plasma phosphate >4.5 mg/dL)

IV. Renewal Criteria [1]

Duration of authorization has not been exceeded *(refer to Section I)*

V. Dosage/Administration [1,6-15]

Indication	Dose
Hyperuricemia due to Tumor Lysis	Administer 0.2 mg/kg intravenously daily for up to 5 days Note: Dosing beyond 5 days or administration of more than one course is not recommended. Elitek is indicated only for a single course of treatment. Alternative dosing: A single fixed-dose of rasburicase (3 to 6 mg) is usually adequate in adult members based on literature support. One dose is frequently adequate. However, additional doses should be considered based upon tumor bulk, hydration status, and presence of acute renal failure.

VI. Billing Code/Availability Information

HCPCS Code:

- J2783 – Injection, rasburicase, 0.5 mg; 1 billable unit = 0.5 mg

NDC(s):

- Elitek 1.5 mg single-dose vial: 00024-5150-xx
- Elitek 7.5 mg single-dose vial: 00024-5151-xx

VII. References

1. Elitek [package insert]. Morristown, NJ; Sanofi-Aventis U.S. LLC.; May 2025. Accessed May 2026.
2. Coiffier B, Altman A, Pui C, et al. Guidelines for the management of pediatric and adult tumor lysis syndrome: an evidence-based review. J Clin Oncol 2008;26:2767-2778.

3. Jones GL, Will A, Jackson GH, Webb NJ, Rule S; British Committee for Standards in Haematology. Guidelines for the management of tumour lysis syndrome in adults and children with haematological malignancies on behalf of the British Committee for Standards in Haematology. Br J Haematol. 2015 Jun;169(5):661-71.
4. Cairo MS, Coiffier B, Reiter A, et al. Recommendations for the evaluation of risk and prophylaxis of tumour lysis syndrome (TLS) in adults and children with malignant diseases: an expert TLS panel consensus. Br J Haematol 2010; 149:578.
5. Cortes J, Moore JO, Maziarz RT, et al. Control of plasma uric acid in adults at risk for tumor lysis syndrome: efficacy and safety of rasburicase alone and rasburicase followed by allopurinol compared with allopurinol alone—results of a multicenter phase III study. J Clin Oncol. 2010;28(27):4207-4213.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Guidelines Version 2.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2026.
7. Giraldez M, Puto K: A single, fixed dose of rasburicase (6 mg maximum) for treatment of tumor lysis syndrome in adults. Eur J Haematol 85: 177– 179,2010.
8. McDonnell AM, Lenz KL, Frei-Lahr DA, et al: Single-dose rasburicase 6 mg in the management of tumor lysis syndrome in adults. Pharmacotherapy 26: 806– 812,2006.
9. Liu CY, Sims-McCallum RP, Schiffer CA: A single dose of rasburicase is sufficient for the treatment of hyperuricemia in patients receiving chemotherapy. Leuk Res 29: 463– 465,2005.
10. Trifilio S, Gordon L, Singhal S, et al: Reduced-dose rasburicase (recombinant xanthine oxidase) in adult cancer patients with hyperuricemia. Bone Marrow Transplant 37: 997– 1001,2006.
11. Hutcherson DA, Gammon DC, Bhatt MS, et al: Reduced-dose rasburicase in the treatment of adults with hyperuricemia associated with malignancy. Pharmacotherapy 26: 242– 247,2006.
12. Hummel M, Reiter S, Adam K, et al: Effective treatment and prophylaxis of hyperuricemia and impaired renal function in tumor lysis syndrome with low doses of rasburicase. Eur J Haematol 80: 331– 336,2008.
13. Reeves DJ, Bestul DJ: Evaluation of a single fixed dose of rasburicase 7.5 mg for the treatment of hyperuricemia in adults with cancer. Pharmacotherapy 28: 685– 690,2008.
14. Campara M, Shord SS, Haaf CM: Single-dose rasburicase for tumour lysis syndrome in adults: Weight-based approach. J Clin Pharm Ther 34: 207– 213,2009.
15. Trifilio SM, Pi J, Zook J, et al: Effectiveness of a single 3-mg rasburicase dose for the management of hyperuricemia in patients with hematological malignancies. Bone Marrow Transplant. 2011 Jun;46(6):800-5. Doi: 10.1038/bmt.2010.212.
16. Larson RA, Pui CH (Feb 2024). Tumor lysis syndrome: Pathogenesis, clinical manifestations, definition, etiology and risk factors. Drews RE, Freedman AS, Poplack DG, Rosmarin AG (Eds.).

In UpToDate. Last updated: May 21, 2026. Accessed: June 16, 2026. Available from: https://www.uptodate.com/contents/tumor-lysis-syndrome-pathogenesis-clinical-manifestations-definition-etiology-and-risk-factors?search=Tumor%20lysis%20syndrome:%20Pathogenesis,%20clinical%20manifestations,%20definition,%20etiology%20and%20risk%20factors&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E88.3	Tumor lysis syndrome

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC